Tecartus

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
WS/2247	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting	15/09/2022	n/a		

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP				
II/0008/G	This was an application for a group of variations. Group of variations including and extension of indication to include treatment of adult patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (B-ALL) for Tecartus and a type IB variation to change the Drug Product Dose specification for the new indication. As a consequence, sections 2.2, 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. Annex II is updated to reflect the new Specific Obligations for the new indication. The Package Leaflet and Labelling are updated in accordance. Version 1.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	21/07/2022	02/09/2022	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Product Name-H-C-Product Number-II-Var.No'
PSUSA/10903 /202201	Periodic Safety Update EU Single assessment - autologous peripheral blood t cells cd4 and cd8 selected and cd3 and cd28 activated transduced with retroviral vector expressing anti-cd19 cd28/cd3-zeta	01/09/2022	n/a		PRAC Recommendation - maintenance

	chimeric antigen receptor and cultured				
IB/0028	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	23/08/2022	n/a		
IB/0027	B.I.b.z - Change in control of the AS - Other variation	09/08/2022	n/a		
WS/2269	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	23/06/2022	n/a		
II/0019	Update of sections 4.8 and 5.1 of the SmPC in order to update the safety and efficacy information based on 24-month follow-up data from all treated patients in cohort 1 of the pivotal clinical study, KTE-C19-102 (ZUMA-2); a Phase 2, multicenter, open-label study evaluating the safety and efficacy of KTE-X19 in subjects with relapsed or refractory (r/r) mantle cell lymphoma (MCL). This submission is in fulfilment of the specific obligation (SOB 004) to confirm the long-term efficacy and safety of Tecartus in adult patients with relapsed/refractory (r/r) MCL. As a consequence Annex II E has been updated with deletion of the fulfilled SOB. In addition, the MAH has taken the opportunity to make minor editorial changes in the SmPC. The RMP version 2.1 has also been submitted.	23/06/2022	02/09/2022	SmPC and Annex II	The updated 24-month follow-up analyses of efficacy were conducted using the modified intent to treat (mITT) analysis set, which consisted of 68 patients treated with Tecartus. In the 24-month follow up analysis, the ORR and CR rates in the 68 patients in the mITT analysis set were 91% and 68% respectively. For more information, please refer to the Summary of Product Characteristics.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0024	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	25/05/2022	n/a		
WS/2194	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	22/04/2022	n/a		
IAIN/0023	A.3 - Administrative change - Change in name of the AS or of an excipient	21/04/2022	02/09/2022	SmPC, Labelling and PL	
II/0016	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	24/03/2022	n/a		
WS/2197	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal	24/02/2022	n/a		

	product and is not related to a protocol				
PSUSA/10903 /202107	Periodic Safety Update EU Single assessment - autologous peripheral blood t cells cd4 and cd8 selected and cd3 and cd28 activated transduced with retroviral vector expressing anti-cd19 cd28/cd3-zeta chimeric antigen receptor and cultured	10/02/2022	n/a		PRAC Recommendation - maintenance
WS/2181	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	27/01/2022	n/a		
WS/2206	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.2 and 4.4 of the SmPC and Annex IID in order to add statements for the use of Tecartus and Yescarta exceptionally during shortage of tocilizumab following the "CAT recommendation for the use of CAR-T cell-based therapies in EU during shortages of tocilizumab". The RMPs for both products are updated accordingly (version 1.2 for Tecartus and version 5.2 for Yescarta). The update of the RMPs for both products (version 1.2 for Tecartus and version 5.2 for Yescarta)	16/12/2021	24/01/2022	SmPC, Annex II and PL	The product information has been amended to reflect that in the exceptional case where tocilizumab is not available due to a shortage that is listed in the European Medicines Agency shortage catalogue, suitable alternative measures to treat CRS instead of tocilizumab should be available on-site. For more information, please refer to the Summary of Product Characteristics.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
II/0012	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	16/12/2021	n/a		
R/0010	Renewal of the marketing authorisation.	16/09/2021	18/11/2021		The CAT and CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, are of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Tecartus, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
N/0011	Transfer of Marketing Authorisation	17/09/2021	24/01/2022	PL	
WS/2071	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	16/09/2021	n/a		

PSUSA/10903 /202101	Periodic Safety Update EU Single assessment - autologous peripheral blood t cells cd4 and cd8 selected and cd3 and cd28 activated transduced with retroviral vector expressing anti-cd19 cd28/cd3-zeta chimeric antigen receptor and cultured	02/09/2021	n/a		PRAC Recommendation - maintenance
IB/0009	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	06/07/2021	n/a		
IB/0005/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	12/05/2021	n/a		
IB/0003	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	23/04/2021	n/a		
II/0001	B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an	22/04/2021	n/a		

	approved protocol				
IB/0004	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	31/03/2021	n/a		
IB/0002	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	09/03/2021	n/a		